7. 510(k) Summary

MAY - 1 2008

As Required By Section 807.92 (c)

Submitter: Custom Spine, Inc.
1140 Parsippany Blvd
Suite 201
Parsippany, NJ 07054

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Date Prepared: April 11, 2008

Device Class: II

Classification Name: Per 21 CFR §888.3080, Intervertebral body fusion device

Classification Panel: Orthopedics

Product Code: MAX

Proprietary Name: PATHWAY

Predicate Devices: Spinal Elements Lucent (K071724), Depuy Acromed™ Stackable Cage™ System (K990148, K001340, K030833)

Device Description: The PATHWAY Interbody Fusion Device is made from Polyetheretherketone (PEEK OPTIMA ™) and contain titanium markers. The titanium markers serve a means for the end user of the device to determine the location of the implant intra-operatively and post- operatively.

The device(s) is rectangular in nature and have various widths, lengths, heights and degrees of lordosis (0 Degree and 6 Degree). The devices contain empty space for the practitioner to insert autogenous bone graft. The devices have serrated teeth on the superior and inferior sides to provide anchorage stability to the vertebrae. They are single use devices.

The 0 Degree PLIF has a width of 10 mm, a length of 23 mm, and ranges in height from 7 to 15 mm.

The 6 Degree PLIF is lordotic in nature and has a width of 8 mm, a length of 23 mm, and ranges in height from 7 to 15 mm

The TLIF is a rectangular in nature and has a width of 10 mm, a length of 28 mm, and ranges in height from 7 to 15 mm.

The implants are provided non-sterile and the instruments are provided cleaned, decontaminated and non-sterile. These devices must be sterilized by the user facility.

Intended Use: The PATHWAY Interbody Fusion Device(s) is intended for spinal fusion procedure at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative Disc Diseases (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

The PATHWAY Interbody Fusion device is intended to be used with supplemental spinal fixation systems that have been cleared for lumbosacral spine (i.e. posterior pedicle screws and rod systems , anterior plate systems, and anterior screw and rod systems. The device(s) is intended to be used with autogenous bone graft.

Patients must have undergone a regiment of at least (6) months of non-operative treatment prior to being treated with the PATHWAY Device.

The PATHWAY device can be used in one of two methods:

Transforaminal Lumbar Interbody Fusion (TLIF)

Used as a TLIF, a single device is implanted in the appropriate location to provide support for a transforaminal approached surgery

Posterior Lumbar Interbody Fusion (PLIF)

Used as a PLIF, multiple devices are implanted in the appropriate locations to provide support to the spine for a posterior surgery.

Materials : This product is manufactured from polyetheretherketone (PEEK OPTIMA) as per ASTM F2026 and contains Titanium (Ti-6Al-4V) as per ASTM F-136 implant grade titanium alloy.

Performance Data: Performance data per ASTM 2077 and ASTM 2267 and compared to the predicate device.

Summary of Technological Characteristics:

Documentation is provided that demonstrates PATHWAY Interbody Fusion Device is substantially equivalent to the predicate devices in terms of materials, design, indications for use, and mechanical properties. The testing information and physiological data support the rational for equivalence with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2008

Custom Spine, Inc.
% Mr. Saad Attiyah
1140 Parsippany Boulevard
Suite 201
Parsippany, NJ 07054

Re: K080281
Trade/Device Name: PATHWAY Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 11, 2008
Received: April 14, 2008

Dear Mr. Attiyah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

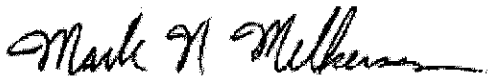
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use

510(k) Number (if known): K080281

Device Name: PATHWAY Intervertebral body fusion device

The PATHWAY Interbody Fusion Device(s) is intended for spinal fusion procedure at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative Disc Diseases (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

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Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K080281